



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0001]

National Mammography Quality Assurance Advisory Committee, Renewal

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; renewal of advisory committee.

SUMMARY: The Food and Drug Administration (FDA) is announcing the renewal of the National Mammography Quality Assurance Advisory Committee by the Commissioner of Food and Drugs (the Commissioner). The Commissioner has determined that it is in the public interest to renew the National Mammography Quality Assurance Advisory Committee for an additional 2 years beyond the charter expiration date. The new charter will be in effect until July 6, 2017.

DATES: Authority for the National Mammography Quality Assurance Advisory Committee will expire on July 6, 2017 unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Sara J. Anderson, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg 66, rm. 1643, Silver Spring, MD, 20993, [Sara.Anderson@fda.hhs.gov](mailto:Sara.Anderson@fda.hhs.gov), 301 796-7047.

SUPPLEMENTARY INFORMATION: Under 41 CFR 102-3.65 and approval by the Department of Health and Human Services under 45 CFR part 11 and by the General Services Administration, FDA is announcing the renewal of the National Mammography Quality

Assurance Advisory Committee. The committee is a statutory Federal advisory committee established to provide advice to the Commissioner.

The Secretary and, by delegation, the Assistant Secretary for the Office of Public Health and Science, and the Commissioner of Food and Drugs are charged with the administration of the Federal Food, Drug and Cosmetic Act and various provisions of the Public Health Service Act. The Mammography Quality Standards Act of 1992 amends the Public Health Service Act to establish national uniform quality and safety standards for mammography facilities. The National Mammography Quality Assurance Advisory Committee advises the Secretary and, by delegation, the Commissioner of Food and Drugs in discharging their responsibilities with respect to establishing a mammography facilities certification program.

The Committee shall advise the Food and Drug Administration on:

- A. Developing appropriate quality standards and regulations for mammography facilities;
- B. Developing appropriate standards and regulations for bodies accrediting mammography facilities under this program;
- C. Developing regulations with respect to sanctions;
- D. Developing procedures for monitoring compliance with standards;
- E. Establishing a mechanism to investigate consumer complaints;
- F. Reporting new developments concerning breast imaging which should be considered in the oversight of mammography facilities;
- G. Determining whether there exists a shortage of mammography facilities in rural and health professional shortage areas and determining the effects of personnel on access to the services of such facilities in such areas;

- H. Determining whether there will exist a sufficient number of medical physicists after October 1, 1999; and
- I. Determining the costs and benefits of compliance with these requirements.

The Committee shall consist of a core of 15 members, including the Chair. Members and the Chair are selected by the Commissioner or designee from among physicians, practitioners, and other health professionals, whose clinical practice, research specialization, or professional expertise includes a significant focus on mammography. Members will be invited to serve for overlapping terms of up to four years. Almost all non-Federal members of this committee serve as Special Government Employees. The core of voting members shall include at least 4 individuals from among national breast cancer or consumer health organizations with expertise in mammography, and at least 2 practicing physicians who provide mammography services. In addition to the voting members, the Committee shall include 2 nonvoting industry representatives who have expertise in mammography equipment. The Committee may include one technically qualified member, selected by the Commissioner or designee, who is identified with consumer interests.

Further information regarding the most recent charter and other information can be found at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/Radiation-EmittingProducts/NationalMammographyQualityAssuranceAdvisoryCommittee/ucm124611.htm> or by contacting the Designated Federal Officer (see FOR FURTHER INFORMATION CONTACT). In light of the fact that no change has been made to the committee name or description of duties, no amendment will be made to 21 CFR 14.100.

This document is issued under the Federal Advisory Committee Act (5 U.S.C. app. 2).

For general information related to FDA advisory committees, please visit us at

<http://www.fda.gov/AdvisoryCommittees/default.htm>.

Dated: August 10, 2015.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

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